leuprolide acetate (Fensolvi)

Commercial Medical Benefit Drug Policy

Place of Service
Office Administration
Infusion Center Administration
Home Infusion Administration
Outpatient Facility Administration

Drug Details

USP Category: HORMONAL AGENTS, SUPPRESSANT (ADRENAL OR PITUITARY)
Mechanism of Action: Gonadotropin releasing hormone (GnRH) agonist
HCPCS:
J1951:Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg
How Supplied:
45 mg of leuprolide acetate supplied in a kit

Condition(s) listed in policy *(see coverage criteria for details)*

- Central Precocious Puberty
- Gender Dysphoria in Adolescents

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

The following condition(s) DO NOT require Prior Authorization/Preservice if ALL its parameters are met, otherwise Prior Authorization/Preservice is required.

Central Precocious Puberty

1. Documented diagnosis of central precocious puberty (neurogenic or idiopathic)

Covered Doses:
Up to 45 mg given subcutaneously once every six months

ICD-10:
E30.1

Gender Dysphoria in Adolescents

Covered Doses:
Up to 45 mg given subcutaneously once every six months

ICD-10:
F64.0, F64.1, F64.2, F64.9

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com
3. Fensolvi (leuprolide acetate) Prescribing Information. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. 11/2022.
4. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017;102(11):3869-3903.
5. World Professional Association for Transgender Health Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 8). 2022. Available at: https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

Review History

Date of Last Annual Review: 2Q2025
Changes from previous policy version:

- No clinical change to policy following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee